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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,250	03/29/2004	Jeffrey W. Chambers	C364.105.101	2755

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

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09/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,250	Applicant(s) CHAMBERS, JEFFREY W.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28-30,32,34-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866). Saltiel discloses a method of deploying a stent within a patient adjacent the ostium using a deployment site locator, abstract. Saltiel discloses a distal end of a guide catheter is used to deliver an expandable site locator to a position adjacent the ostium, col. 4, lines 25-33. Saltiel additionally discloses deploying the stent at the desired location once the site locator is expanded and contacts bodily structures immediate the ostium, col. 6 lines 13-16. The stent is then delivered to the desired location at the ostium (col. 6, lines 29-31) and then the site locator is removed from the patient, col. 6, lines 35-40. The use of "fixed relative to" and "fixed distance" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, since the stent is positioned adjacent to, it at a "fixed position" relative to the site locator. Regarding claim 30, the adjustment of the stent to place it is done by visual indication, col. 2, lines 39-43. With respect to claim 32, Saltiel does disclose if radiopaque techniques are used for deployment, the deployment site locator and stent have radio-opaque markers used, col. 6, lines 24-26. Regarding claim 35, Saltiel additionally discloses a guidewire can be used such that the guide catheter can be

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delivered over the guidewire, col. 5, lines 37-39,55-59. However, Saltiel fails to disclose deploying a site locator having a plurality of rods to the location to be treated. Zikorus shows the end of a catheter adjacent an ostium of a vessel, Fig. 3 and teaches delivering the catheter as such, abstract, paragraph 10. A deployment site locator **56** is delivered through the catheter and includes a plurality of rods **58**. Zikorus teaches the site locator with the rods provides an alternative means to determine a vessel location without using large ultrasound or other similar imaging equipment, paragraph 8. Zikorus shows (Figs. 6-9,11) a side view of the site locator with a base **106** and how (paragraph 27) the rods expand relative to one another to a maximum dimension. Zikorus et al. also teaches the site locator provides feedback such that a position of the ostium is determined by contacting vessel walls, paragraphs 11,15,29. It would have been obvious to one of ordinary skill in the art to use an alternative site detection means that expands having rods as taught by Zikorus et al. in the method of Saltiel to deliver a stent to a location adjacent the ostium. Regarding claim 36, the stent would be delivered over the guidewire and through the deployment site locator of Zikorus as seen in Fig. 8. With respect to claims 40,43-45 since the rods are designed to deflect outward, it can be construed that they have a spring action and the rods have a length such that the intermediate section would engage a portion of the proximal ostium, see Fig. 6a. Self-expanding material that display this property is well known in the art. Regarding claim 42, since Saltiel discloses (col. 5, lines 59-61) the stent is located “distal” to the vessel where it is to be deployed, it is not being considered to be placed in the target vessel until the rods are extended and the ostium location is determined.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866) as applied to claim 30 above, and further in view of Close et al. (6532380). Saltiel as modified by Zikorus et al. is explained above. It is noted that Saltiel discloses visual indication is used to position the stent and that radiographic techniques or modalities are used, col. 6, lines 24-30. However, Saltiel in view of Zikorus do not state that x-ray imaging is used for adjusting the position of the stent. Close et al. teach that x-ray imaging is used in placement of a stent, col. 3, lines 62-67, col. 6, lines 33-36. It would have been obvious to one of ordinary skill in the art to use x-ray imaging as taught by Close et al. in the method of positioning a stent at an ostium disclosed by Saltiel and modified in view of Zikorus et al. such that an accurate placement can be achieved and known by the surgeon by the results given by the x-ray.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saltiel (6458151) in view of Zikorus et al. (2002/68866) as applied to claim 28 above, and further in view of Shaknovich (5749890). Saltiel as modified by Zikorus et al. is explained above. It is noted that Saltiel discloses the aorta may be a location where the positioning of the stent is performed near, col. 1. However, Saltiel in view of Zikorus do not explicitly state the coronary artery and the aorta wall is of the ostium where the position of the stent is done. Shaknovich teaches that the target vessel to be stented is the coronary artery and the vascular structure proximate the ostium is the aorta wall, col. 6, lines 27-29, 41-44. It would have been obvious to one of ordinary skill in the art to surgically implant a stent in the ostium near the aorta wall as taught by Shaknovich

using the method of positioning a stent at an ostium disclosed by Saltiel and modified in view of Zikorus et al. such that a lesion in this region is treated.

Response to Arguments

Applicant's arguments filed 6/12/08 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant attempts to point out differences in use of the Zikorus et al. apparatus. However, Applicant must be reminded the structure of Zikorus is only being incorporated into the method of delivering a stent as disclosed by Saltiel and that Saltiel discloses the deployment site locator is expanded prior to deployment of the stent and contacts bodily structures of the patient, col. 2, lines 26,27. Thus, the steps would be followed by Saltiel's method of delivering a stent, but just uses alternatively an expandable rod system. Applicant argues an engaging member of the Zikorus system is not part of the electrodes. However, that is irrelevant because the hook can be considered part of the "plurality of rods" as claimed. Applicant is not being given any special definition for "rod" and since the element is clearly an elongate structure it can be considered a "rod". Applicant then attempts to argue that the modification makes Saltiel's method inoperable stating the use of Zikorus system of elements would not allow for the distance from the expandable member to the stent to be known. Applicant

is mistaken since Zikorus's apparatus clearly provides the surgeon with the ability to know distances for example Zikorus teaches the electrode system permits anatomical locations to be marked, paragraphs 32,37. Thus, the modification would still enable the method of Saltiel to perform the proper delivery of the stent.

Regarding Applicant's comments regarding the new claims, it is noted that arguments were made against Saltiel. However, the rejection was the combination and the features claimed can be found in the modifying structure of Zikorus's device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian E Pellegrino/
Primary Examiner, Art Unit 3738